LISTING OF CLAIMS

1. (Withdrawn) An isolated Ozz protein.

2. (Withdrawn) The Ozz protein of claim 1 which is a human Ozz protein.

3. (Withdrawn) The nucleic acid of claim 11 wherein the Ozz protein has an amino acid sequence as depicted in SEQ ID NO:4.

4. (Withdrawn) The Ozz protein of claim 1 which is a mouse Ozz protein.

5. (Withdrawn) The nucleic acid of claim 13 wherein the Ozz protein has an amino acid sequence as depicted in SEQ ID NO:2.

6. (Withdrawn) The Ozz protein of claim 4 which is encoded by a nucleic acid having a sequence as depicted in SEQ ID NO:1, or by a nucleic acid which is hybridizable under stringent conditions with a nucleic acid having a sequence as depicted in SEQ ID NO:1 or its complement.

7. (Withdrawn) A fragment, analog, or derivative of the Ozz protein of claim 1, which fragment, analog, or derivative has the ability to bind a protein selected from the group consisting of β-catenin, myosin, c-Nap, and Alix.

8. (Withdrawn) A polypeptide fragment of an Ozz protein, wherein the fragment has a property selected from the group consisting of:

a) having about 40% sequence identity to a duplicated neuralized homology repeats (NHRs) of neuralized protein of Drosophila;

b) comprising a stretch of about 30 amino acids at the C-terminus homologous to two regions of neuralized proteins;

c) comprising an amino acid sequence selected from the group consisting of SEQ ID NOS:5, 7, 9, and 11;

d) comprising an amino acid sequence selected from the group consisting of GTRATR (SEQ ID NO:19), GVCFSR (SEQ ID NO:20), GQPEA (SEQ ID NO:21), KGLKDFCKY (SEQ ID NO:22), PSLQTLCRLVIQRSMVHRLAIDGLHLPKELKDFCKYE (SEQ ID NO:23), and SLxxxCxxxI (SEQ ID NO:24); and

e) specific binding activity with an anti-Ozz antibody.

9. **(Currently amended) An isolated nucleic acid encoding an Ozz protein wherein the Ozz protein is expressed only in cardiac and skeletal muscle, comprises about 285 amino acids, and shares about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:2 or SEQ ID NO:4.**

10. (Original) The nucleic acid of claim 9 which is a cDNA.

11-12. (Canceled)

13. (Previously presented) The nucleic acid of claim 9, wherein the Ozz protein is a mouse Ozz protein with a molecular weight of about 30 kilo-Daltons (kDa).

14. (Original) The nucleic acid of claim 13 which comprises a nucleotide sequence as depicted in SEQ ID NO:1.

15. (Previously presented) A vector comprising a nucleic acid encoding a fragment of an Ozz protein operatively associated with an expression control sequence, wherein the fragment of an Ozz protein has the ability to bind a protein selected from the group consisting of β-catenin, myosin, c-Nap, and Alix; wherein full-length Ozz protein

shares about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:2 and comprises about 285 amino acids.

16. (Original) The vector according to claim 15, wherein the fragment of an Ozz protein is a full length Ozz protein.

17. (Original) A host cell transfected with the vector of claim 15.

18. (Withdrawn) A non-human animal transformed with the vector of claim 15, wherein the animal expresses an Ozz protein.

19. (Original) A method for producing Ozz protein comprising isolating Ozz protein produced by the host cells of claim 17, wherein the host cells have been cultured under conditions that provide for expression of the Ozz protein by the vector.

20. **(Currently amended) An isolated nucleic acid consisting of at least ten consecutive nucleotides of SEQ ID NO:1 that hybridizes under stringent conditions with a nucleic acid having a nucleotide sequence as depicted in SEQ ID NO:1 or SEQ ID NO:3, with the proviso that the isolated nucleic acid is not a PPCA exon Ia, wherein the stringent conditions are hybridization at 68°C in 0.2XSSC or 42°C in 50% formamide, 4XSSC.**

21. (Canceled)

22. (Withdrawn) An isolated Ozz muscle-specific promoter.

23. (Withdrawn) A vector comprising a heterologous gene operatively associated with the muscle-specific promoter of claim 22.

24. (Withdrawn) An antibody that specifically binds to the Ozz protein of claim 1.

25. (Withdrawn) A method for detecting an Ozz protein comprising detecting binding of the antibody of claim 24 to a protein in a sample suspected of containing an Ozz protein, wherein the antibody is contacted with the sample under conditions that permit specific binding with any Ozz protein present in the sample.

26. (Withdrawn) A method for detecting expression of Ozz comprising detecting mRNA encoding Ozz in a sample from a cell suspected of expressing Ozz.

27. (Withdrawn) The method according to claim 28 wherein mRNA encoding Ozz is detected by hybridization to an Ozz-specific nucleic acid.

28. (Withdrawn) The method according to claim 27 wherein the Ozz-specific nucleic acid is Ozz cDNA.

29. (Withdrawn) A method for detecting damage to muscle tissue comprising detecting an increase in the level of Ozz protein in a blood or a blood fraction, wherein the presence of an increase in the level of Ozz in blood or a blood fraction indicates damage to muscle tissue.

30. (Withdrawn) The method according to claim 29 wherein the muscle is the heart.

31. (Withdrawn) A method for detecting a disease associated with a defect in Ozz expression in a subject, which method comprises detecting an abnormal level or localization of Ozz in muscle cells from a subject.

32. (Withdrawn) The method according to claim 31, wherein the disease is galactosialidosis.

33. (Withdrawn) The method according to claim 32, wherein the muscle cells are from the atrium of the heart.

34. (New) The nucleic acid of claim 9, wherein the Ozz protein is a human Ozz protein.

35. (New) The nucleic acid of claim 34, which comprises a nucleotide sequence as depicted in SEQ ID NO:3.

SUMMARY OF ARGUMENTS

Rejection of claims 9-10, 13, 15-17, 19, and 20 under 35 U.S.C. § 112, ¶ 1

- **Examiner:** Undue experimentation must be performed to search and screen for the specific nucleotides that result in an isolated nucleic acid encoding a functional Ozz protein that shares 90%-92% sequence similarity with SEQ ID NO:2 (Office Action, p. 3)
- **Response:**
  - **Ozz is a novel nucleic acid and protein with tissue-specific expression**
    - The claim is directed to Ozz proteins "observed in heart and skeletal muscle," specification, p. 8, ll. 1-2
    - Accordingly, nature, in the course of evolution, has performed the "search and screen"
  - **Isolating, sequencing, and characterizing the sequence relationship to SEQ ID NO:2 requires less than routine skill in the art**
  - **"Ozz encompasses polypeptides having about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:2" (specification, p. 7, ll. 22-25), not "about 90-92% sequence similarity" as stated in the Office Action**

Rejection of claim 20 under 35 U.S.C. § 112, ¶ 1

- **Examiner:** Undue experimentation is required to determine "the specific hybridization conditions that would effectively screen out any hybridization to any region of the PPCA exon Ia" (Office Action, p. 4)
- **Response:**
  - **The rejection is not directed to the subject matter as claimed**
    - All that is required of the skilled artisan is to recognize the PPCA exon 1 and exclude it from within the scope of the claimed subject matter. No determination of hybridization conditions is required.
  - **The PPCA exon Ia is excluded from the claims to avoid prior art**
  - **One of ordinary skill in the art could easily determine, from a synthetic protocol or by routine sequencing, whether the sequence of a nucleic acid that hybridizes under the recited conditions to the nucleotide sequence of SEQ ID NO:1 is the PPCA exon Ia**

PROPOSED CLAIM AMENDMENTS

- Amended claims 9 and 20 recite both murine and human sequences
  - SEQ ID NO:4 may be added to claim 9 because SEQ ID NOS:2 and 4 are related to each other by the recited structural characteristics (90% sequence identity, 92% sequence similarity)
  - Claim 9 would thus define a genus that includes both SEQ ID NOS:2 and 4
  - SEQ ID NO:3 may be added to claim 20 to define a genus that includes SEQ ID NOS:1 and 3 (restriction in such a case is improper; election of species is proper)